

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION  
OF: WENZEL ET AL.  
SERIAL NO. 09/782,306  
FILED: FEBRUARY 14, 2001  
FOR: NOVEL USE OF FLAVONES

DOCKET NO.: PF 51202  
CONFIRMATION NO.: 2453  
GROUP ART UNIT: 1623  
EXAMINER: D. KHARE

Honorable Commissioner  
for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. §1.181

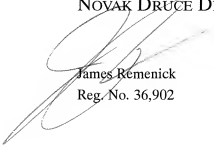
Sir:

Applicants hereby petition to the Honorable Commissioner to withdraw the above-identified pending application from final rejection, and to require the Examiner to provide a non-final action.

On the facts which are summarized below, applicants respectfully urge that their amendment dated July 10, 2006, did not necessitate the new ground of rejection which was raised by the Examiner in the final Office action of September 22, 2006, and thus the Office action asserting such a new ground should have been a non-final rejection to provide applicants with a full and fair time period to respond to such new ground of rejection.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 14.1437. Please credit any excess fees to such deposit account.

Respectfully submitted,  
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Encl.: Marked-up copy of Claim 1 as presented on July 10, 2006

JR/BAS

SUMMARY OF MATERIAL FACTS:

1. The Examiner issued a non-final Office action on April 10, 2006, rejecting then pending Claims 1, 2 and 13 based on

- (a) the teaching of *Koda* (abstract, *Taisha* 10(5), 730-9 (1973)); and
- (b) the teaching of *Gionfriddo et al.* (abstract, *Essenze, Derivati Argumari*, 66(4), 404-416 (1996)).

2. On July 10, 2006, applicants submitted a timely reply in which Claims 2 and 13 were canceled and Claim 1 was amended as indicated in the attached marked-up version of Claim 1.<sup>1)</sup>

3. On September 22, 2006, the Examiner issued a final Office action withdrawing all previous rejections. However, Claim 1 was rejected under Section 102(b) based on the teaching of *Watanabe et al.* (US 5,650,433), a reference which was newly introduced into the proceedings by the Examiner at the time of the final action.

4. This Petition follows.

M E M O R A N D U M

It is applicants position that the amendment of Claim 1 which was submitted with the reply dated July 10, 2006, did not necessitate the new ground of rejection, ie. the rejection of Claim 1 under 35 U.S.C. §102(b) based on the teaching of *Watanabe et al.* which was raised by the Examiner for the first time in the final Office action, and that the finality of said Office action with such new ground is thus improper.



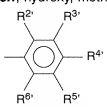
MPEP §706.07(a) sets forth

*Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).*

As shown in the enclosed marked-up copy of Claim 1 as presented with applicants' reply dated July 10, 2006, applicants' amendment effected the following changes:

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1) The marked-up version of Claim 1 is a copy of the claim as presented in the listing of claims enclosed with applicants' paper dated July 10, 2006.

Version pre-July 10, 2006		Amended Version	
A composition for ...		A <u>neutraceutical</u> composition for ...	
R <sup>1</sup> and R <sup>4</sup>	either hydrogen or <b>together a bond</b> ,	R <sup>1</sup> and R <sup>4</sup>	together a bond
R <sup>5</sup> , R <sup>6</sup> , R <sup>7</sup> , R <sup>8</sup>	independently of each other <b>hydrogen</b> , hydroxy or methoxy; in addition R <sup>7</sup> represents a sugar substituent,	R <sup>5</sup> , R <sup>6</sup> , R <sup>7</sup> , R <sup>8</sup>	hydrogen
R <sup>2</sup>	hydrogen, hydroxy, methoxy, or 	R <sup>2</sup>	
R <sup>3</sup>	<b>hydrogen</b> , hydroxy, methoxy, or 	R <sup>3</sup>	hydrogen
R <sup>2</sup> , R <sup>3</sup> , R <sup>5</sup> , and R <sup>6</sup>	<b>hydrogen</b> , hydroxy or methoxy	R <sup>2</sup> , R <sup>3</sup> , R <sup>5</sup> , and R <sup>6</sup>	hydrogen
R <sup>4</sup>	<b>H</b> , flavone, 5-OH-flavone, 7-OH-flavone and 7,8-(OH) <sub>2</sub> -flavone	R <sup>4</sup>	hydrogen
with the proviso, that R <sup>2</sup> or R <sup>3</sup> is represented by the phenyl-ring optionally substituted		<i>[although no longer recited, the proviso remains to be met]</i>	

The foregoing summary shows that the subject matter of Claim 1 as amended on July 10, 2006, is squarely within the realm of Claim 1 as pending prior to July 10, 2006. As such, applicants' amendment cannot be deemed to have necessitated the rejection which was newly raised by the Examiner. Moreover, the rejection which was newly raised by the Examiner was not based on information submitted in an information disclosure statement filed during the referenced period. Rather, the rejection was based on information which was introduced into the proceedings by the Examiner at the time of the final rejection.

MPEP §706.07(c) explains

*Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in reply to this action the applicant should amend with a view to avoiding all the grounds of rejection*

*and objection. Switching from one subject matter to another in the claims presented by applicant in successive amendments, or from one set of references to another by the examiner in rejecting in successive actions claims of substantially the same subject matter, will alike tend to defeat attaining the goal of reaching a clearly defined issue for an early termination, i.e., either an allowance of the application or a final rejection*

It is respectfully submitted that applicants, in their response to the non-final Office action of April 10, 2006, clearly met their duty to “*amend with a view to avoiding all the grounds of rejection and objection.*” In contrast thereto, the Examiner is switching “*from one set of references to another ... in rejecting in successive actions claims of substantially the same subject matter.*”

MPEP §706.07(c) also clarifies that

*... in every case the applicant is entitled to a full and fair hearing, and that a clear issue between applicant and examiner should be developed, if possible, before appeal.*

The fact that the Examiner raised a new rejection, based on prior art not of record, in a final action is deemed to deprive applicants of their right to a full and fair hearing on the issue to which they are entitled. Moreover, the Examiner's action is deemed to prevent that the newly raised issue is clearly developed between the Examiner and applicants prior to appeal.

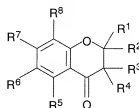
### C O N C L U S I O N

Applicants therefore respectfully request that the finality of the Examiner's action dated September 22, 2006, be withdrawn and that the application be returned to the Examiner for entry and full consideration of applicants' reply of even date with this petition as a timely reply under Rule 111. Favorable action is respectfully solicited.

## APPENDIX I:

MARKED-UP COPY OF CLAIM 1 AS PRESENTED ON JULY 10, 2006:

1. (currently amended) A neutraceutical composition for inhibiting COX-2 biosynthesis or COX-2- and NF $\kappa$ B-biosynthesis comprising a therapeutically effective amount of the compound of formula I

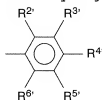


wherein

R<sup>1</sup> and R<sup>4</sup> represent ~~either hydrogen or~~ together a bond,

R<sup>5</sup>, R<sup>6</sup>, R<sup>7</sup>, R<sup>8</sup> represent ~~independently of each other~~ hydrogen, hydroxy or methoxy, in addition R<sup>7</sup> represents a sugar substituent,

R<sup>2</sup> represents and R<sup>3</sup> ~~represent hydrogen, hydroxy, methoxy, or~~



wherein R<sup>2'</sup>, R<sup>3'</sup>, R<sup>4'</sup>, R<sup>5'</sup>, and R<sup>6'</sup> are ~~independently of each other~~ hydrogen, hydroxy or methoxy, wherein R<sup>4'</sup> is H, flavone, 5-OH-flavone, 7-OH-flavone and 7,8-(OH)<sub>2</sub>-flavone, with the proviso, that R<sup>2</sup> or R<sup>3</sup> is represented by the phenyl-ring optionally substituted

R<sup>3</sup> represenets hydrogen.

and a pharmaceutically acceptable carrier.